

### AMENDMENTS

Please amend the above-identified application as follows:

#### Amendments to the claims:

This listing of claims will replace all prior versions, and listings of claims in the application:

1. (currently amended): A method ~~Method~~ for selecting a particular population of women having a risk of developing obstetric or gynecologic pathologies indicated as an OR value equal or higher than 5.5, which value is calculated as the ratio between respectively the percentage of women having ~~no~~ pathologies and those having no pathologies, said method comprising the following steps in order:
  - a) determining ~~the~~ a levels of sialidase activity and/or a level of prolidase activity in samples of ~~cervic~~-vaginal fluid;
  - b) determining a ~~the~~ pH value of said samples; and
  - c) selecting ~~the~~ samples having a level of sialidase activity ~~value~~ equal or above 5.0 nmol, wherein said sialidase activity is expressed as nanomoles of methoxyphenol produced from conversion of sialidase and/or a level of prolidase activity ~~level~~ equal or above 1500 mOD for prolidase and a  $\text{pH} \geq 5.0$ .
2. (currently amended): The method ~~Method~~ as set forth in claim 1, in which the pH of said samples selected in step c) is  $\geq 5.0$  and  $\leq 7.0$ , ~~preferably  $\geq 5.0$  and  $\leq 6.0$ , more preferably  $\geq 5.0$  and  $\leq 5.5$ .~~
3. (currently amended): The method ~~Method~~ as set forth in claim 1, in which after step ~~the a)~~ phase a score of said levels of sialidase and/or prolidase activity is determined.

4. (canceled)
5. (currently amended): The method ~~Method~~ as set forth in claim 1, in which the obstetric or gynecologic pathologies comprise: low birth weight (LBW), very low birth weight (VLBW) preterm delivery (PTD), early preterm delivery (EPTD), premature rupture of membranes, preterm premature rupture of membranes, intraamniotic infections, spontaneous abortion, endometritis, obstetric surgery infections, post-partum or post-gynecologic surgery infections, pelvic surgery infections, upper genital tract infections which cause infertility, pelvic inflammatory disease (PID), annexitis, cervicitis, sexually transmitted diseases and infections, ~~malignancies of the urogenital tract or~~ cervical cancer.
6. (currently amended): The method ~~Method~~ as set forth in claim 1, in which said population of women has the risk of said pathologies at a period of gestation less than 37 weeks, ~~preferably less than 35 weeks, more preferably less than 32 weeks.~~
7. (currently amended): The method ~~Method~~ as set forth in claim 1, in which said method is carried out in samples of ~~erve~~-vaginal fluid of pregnant women.
8. (currently amended): The method ~~Method~~ as set forth in claim 7, in which said method is carried out in samples of ~~erve~~-vaginal fluid of women in the first or second trimester of gestation.
9. (currently amended): The method ~~Method~~ as set forth in claim 7, in which said method is carried out in samples of ~~erve~~-vaginal fluid of women from the sixth to the twenty-fourth full week of gestation.

10. (currently amended): The method ~~Method~~ as set forth in claim 1, in which said method is carried out in samples of ~~eeve~~-vaginal fluid of non-pregnant women.

11. (currently amended): The method ~~Method~~ as set forth in claim 1, in which said OR value is calculated and corrected by a standard factor by the SPSS computer statistic program.

12. (currently amended): A method ~~Method~~ for selecting a particular population of women having a risk of developing, VLBW, delivery at < 37 weeks<sup>2</sup>-gestation, < 35 weeks<sup>2</sup> gestation or < 32 weeks<sup>2</sup> gestation, comprising the following steps in order:

a) determining the levels of sialidase and/or prolidase activity in samples of ~~eeve~~-vaginal fluid;

b) determining the pH value of said samples; and

c) selecting the samples having a  $\text{pH} \geq 5.0$  and a sialidase value above 0.19 nmol of methoxyphenol and/or a prolidase value above 22 mOD.

13. (currently amended): The method ~~Method~~ according to claim 12, wherein the step c) comprises selecting the samples having a  $\text{pH} \geq 5.0$ , sialidase level of over 2.50 nmol of methoxyphenol or a prolidase level of over 1000 mOD.

14. (currently amended): The method ~~Method~~ according to claim 12, wherein the step c) comprises selecting the samples having a  $\text{pH} \geq 5.0$ , a sialidase value above 0.19 nmol or 0.38 nmol or 2.5 nmol of methoxyphenol when it is selected or a prolidase value of over 1000 mOD.

15. (currently amended): The method ~~Method~~ according to claim 12, wherein ~~the~~ step c) comprises selecting the samples having a pH  $\geq 5.0$ , a sialidase value of 0.38 nmol of methoxyphenol and a prolidase value of over 22 mOD or over 44 mOD or over 1000 mOD or over 1500 mOD or over 2000 mOD.

16. (currently amended): The method ~~Method~~ according to claim 12, wherein said risk is indicated as OR value equal or higher than 5.5, ~~which value is calculated preferably by the SPSS computer statistic program.~~

17. (withdrawn): Kit for the determination of women having a risk of developing obstetric or gynecologic pathologies indicated as OR value higher than 5.5, calculated preferably by the SPSS computer statistic program, comprising a sialidase and/or prolidase activity assay in solution that includes a colorless substrate solution in which to inoculate the biologic sample; a developing solution in a container equipped with dispenser; a reference scale to correlate the level of sialidase activity equal or above 0.19 nmol of methoxyphenol and/or the level of prolidase equal or above 22 mOD with the intensity of the developed color; a pH indicator; a reference scale to correlate the pH detected by said indicator with a pH  $\geq 5.0$  and an illustrative leaflet containing the instructions for the proper use of the kit.

18. (withdrawn): Kit according to claim 17, wherein said kit is used with a sample of body fluid of women.

19. (withdrawn): Kit according to claim 17, wherein said body fluid is a vaginal fluid.
20. (withdrawn): Kit according to claim 17, wherein said pH indicator comprises a revealing paper with a turning interval in the range between 5.0 and 7.0, preferably between 5.0 and 6.0, more preferably between 5.0 and 5.5.
21. (withdrawn): Kit according to claim 17, wherein said reference scale for the sialidase and/or prolidase activity reports standard values associated with enzyme detecting colors.
22. (withdrawn): Kit according to claim 21, wherein said reference scale for pH value associates said turning interval with a particular color intensity of the same color.
23. (withdrawn): Kit according to claim 17, wherein said illustrative leaflet correlates the enzymatic activity with the pH value in order to evaluate the risk of pathologies as: absent or low (-), medium (+), high (++), very high (+++).
24. (withdrawn): Kit according to claim 16, including a test on solid support, preferably on reactive strip or platform test, for the determination of the sialidase and/or prolidase activity.
25. (withdrawn): Kit according to claim 17, comprising as chromogenic or fluorogenic substrate for the determination of sialidase activity a reagent chosen in the

group comprising: 2-(3'-methoxyphenyl)-N-acetyl-D-neuraminic acid, 2-O-(o-nitrophenyl)-alpha-D-N-acetyl neuraminic acid, 2'-(4-methylumbelliferyl)-alpha-D-N-acetyl neuraminic acid sodium salt, 5-bromo-4-chloro-3-indolyl-alpha-D-N-acetyl neuraminic acid.

26. (withdrawn): Kit according to claim 25, comprising as chromogenic or fluorogenic substrate for the determination of prolidase activity a reagent chosen in the group comprising: L-proline-para-nitroanilide, L-proline-beta-naphthylamide, N-benzyloxycarbonyl-L-prolyl-beta-naphthylamide, N-benzyloxycarbonyl-L-proline-para-nitrophenyl ester, hydroxy-L-prolyl-beta-naphthylamide, L-proline-7-amido-4-methyl-coumarin, L-proline-4-methoxy-beta-naphthylamide.

27. (withdrawn): Kit for the determination of women having a risk of developing LBW, VLBW, PTD, delivery at < 37 weeks' gestation, < 35 weeks' gestation or < 32 weeks' gestation, comprising a sialidase and/or prolidase activity assay in solution that includes a colorless substrate solution in which to inoculate the biologic sample; a developing solution in a container equipped with dispenser; a reference scale to correlate the level of sialidase activity equal or above 0.19 nmol of methoxyphenol and/or the level of prolidase equal or above 22 mOD with the intensity of the developed color; a pH indicator; a reference scale to correlate the pH detected by said indicator with a pH  $\geq$  5.0 and an illustrative leaflet containing the instructions for the proper use of the kit.

28. (currently amended): A method ~~Method~~ for selecting a particular population of women having a risk of developing obstetric or gynecologic pathologies indicated as OR value equal or higher than 5.5, which value is calculated as the ratio between respectively

the percentage of women having ~~no~~ pathologies and those having no pathologies,  
comprising the following steps in order:

a) determining a ~~evaluation~~ of the levels of sialidase enzyme activity in one or more  
said samples of cervo-vaginal fluid:

b) providing ~~provision~~ of a value indicative of the risk, wherein said value indicative  
of the risk is obtainable by a method comprising the steps of:

i) providing a group of women who have body fluid samples that have  
sialidase enzyme activity;

ii) evaluating the levels of sialidase enzyme activity in such a group;

iii) calculating the percentage of women of said group who had said  
pathologies and who had no pathologies; and

iv) calculating a value and its correction with a standard factor on the basis of  
the percentage obtained in step iii) in order to evaluate the value indicative of  
the risk;

c) comparing said levels of sialidase enzyme activity obtained from the step a) with  
said value indicative of the risk provided in step b);

d) calculating ~~ealeulation~~ of risk factor, wherein said value indicative of the risk is  
obtainable by a method comprising the steps of:

i) providing a group of women whose body fluid samples have sialidase  
enzyme activity;

ii) evaluating the levels of sialidase enzyme activity in such a group;

iii) calculating the percentage of women of said group who had said  
pathologies and who had no pathologies; and

~~iv) calculating a value and its correction with a standard factor on the basis of the percentage obtained in step iii) in order to evaluate the value indicative of the risk; and~~

e) selecting a particular population of women if said particular population of women possesses said risk factor.

29. (new) The method as set forth in claim 1, in which the pH of said samples selected in step c) is  $\geq 5.0$  and  $\leq 6.0$ .

30. (new) The method as set forth in claim 1, in which the pH of said samples selected in step c) is  $\geq 5.0$  and  $\leq 5.5$ .

31. (new). The method as set forth in claim 1, in which said population of women has the risk of said pathologies at a period of gestation less than 35 weeks.

32. (new). The method as set forth in claim 1, in which said population of women has the risk of said pathologies at a period of gestation less than 32 weeks.

33. (new) The method according to claim 16, wherein said OR value is calculated preferably by the SPSS computer statistic program